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10/577,119	04/13/2007	Gary Kevin Robinson	05794.00004	1176
29880 7590 07/14/2009 FOX ROTHSCHILD LLP			EXAMINER	
PRINCETON PIKE CORPORATE CENTER			PORTNER, VIRGINIA ALLEN	
2000 Market Street Tenth Floor		ART UNIT	PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/577,119 ROBINSON ET AL. Office Action Summary Examiner Art Unit GINNY PORTNER 1645 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 13 April 2007. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-20 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) \_\_\_\_\_ is/are rejected 7) Claim(s) is/are objected to. 8) Claim(s) 1-20 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Attachment(s)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date. \_\_\_\_\_.

6) Other:

5) Notice of Informal Patent Application

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### DETAILED ACTION

#### Election/Restrictions

 This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- Method of regulating quorum sensing, the regulating being modulation through disruption of the quorum sensing signal pathway resulting in down regulation of quorum sensing by a <u>peptide hydrolase</u>. (claims 2,3-8).
- 3. Method of regulating quorum sensing, the regulating being modulation through disruption of the quorum sensing signal pathway resulting in down regulation of quorum sensing by a <u>peptide hydrolase together with a carrier</u> and any one or more of a detergent, surfactant, biocide, fungicide, antibiotic or a mixture thereof; and any one or more of a pH regulator, perfume, dye or colorant. (claims 9-12, 15).
- 4. Method of regulating quorum sensing, the regulating being modulation through disruption of the quorum sensing signal pathway operon by inserting an <u>exogenous gene</u> into the operon control for **down regulation of** quorum sensing (claims 12, 16-19).
- Method of regulating quorum sensing, the regulating being modulation through inhibiting
  a peptide hydrolase associated with a quorum sensing signal pathway resulting in up-regulation
  of quorum sensing by a peptide hydrolase inhibitor (claims 2,13-15, and 20).

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 Method of regulating quorum sensing, the regulating being modulation through disruption of the quorum sensing signal pathway operon by inserting an <u>exogenous gene</u> into the operon control for <u>up regulation of quorum sensing</u> (claims 2, 13, 16-19).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP \$ 809.02(a).

- 7. The claims are deemed to correspond to the species listed above in the following manner:
  Please see claims listed above with each listed species of invention.
  The following claim(s) are generic: Claim 1 is generic.
- 8. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The special technical feature of first appearing invention defined by claims 1 and 3 is described by Berka et al (US PG-Pub 2003/0027310A1), wherein Berka et al modulates, specifically down regulates guorum sensing and biofilm

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formation by administering or contacting a surface with a Lactono-hydrolase, a type of peptide

hydrolase (see abstract) and following paragraphs:

[0023] The term "<u>lactonohvdrolase</u> activity" is defined herein as a hydrolase activity which catalyzes the hydrolysis of aldonate and aromatic lactones to the corresponding carboxylic acids. For purposes of the present invention, <u>lactonohvdrolase</u> activity is determined according to the procedure described by Fishbein and Bessman, 1966, Journal of Biological Chemistry 241: 4835-4841, where the hydrolysis of D-galactono-gamma-lactone is measured.

[0024] In a first embodiment, the present invention relates to isolated polypeptides having an amino acid sequence which has a degree of identity to amino acids 18 to 400 of SEQ ID NO. 2 (i.e., the mature polypeptide) of at least about 95%, and preferably at least about 97%, which have lactonohydrolase activity (hereinafter "homologous polypeptides"). In a preferred embodiment, the homologous polypeptides have an amino acid sequence which differs by five amino acids, preferably by four amino acids, more preferably by three amino acids, enor more preferably by two amino acids, and most preferably by one amino acid from amino acids 18 to 400 of SEQ ID NO. 2. For purposes of the present invention, the degree of identity between two amino acid sequences is determined by the Clustal method (Higgins, 1989, CABIOS 5: 151-153) using the LASERGENE.TM. MEGALIGN.TM. software (DNASTAR, Inc., Madison, Wis.) with an identity table and the following multiple alignment parameters: Gap penalty of 10 and gap length penalty of 10. Pairwise alignment parameters were Ktuple=1, gap penalty=3, windows=5, and diagonals=5.

[0176] The present invention also relates to methods for preventing biofilm development on a liquid-solid interface by one or more microorganisms, comprising administering an effective amount of a composition comprising one or more polypeptides having <a href="mailto:lackgraph">lackgraph</a> a carrier to the liquid-solid interface to degrade one or more lactones produced by the one or more microorganisms, wherein the one or more lactones are involved in the formation of the biofilm

[0177] The lactone may be any lactone involved in biofilm formation. In a preferred embodiment, the lactone is a homoserine lactone. In a more preferred embodiment, the lactone is N-(3-oxododecanoyl)-L-homoserine lactone. In another more preferred embodiment, the lactone is N-butryl-L-homoserine lactone.

Therefore the claimed inventions are not so linked by a special technical feature that makes a contribution over the prior art. Lack of Unity of invention exists in light of the description and teachings of Berka et al (US PG-Pub 2003/0027310, published February 6, 2003).

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Please select the desired species of invention, and a specific combination for examination based upon the species selected and designate what claims read on the elected species.

9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

## General Observations/ Specification

11. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. The hyperlinks located in paragraphs [012], [014], [028] and [031] must be removed.

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 Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862.

The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated  $\,$ 

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/ Examiner, Art Unit 1645

July 10, 2009

/Robert B Mondesi/

Supervisory Patent Examiner, Art Unit 1645